

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 14, 2020

Michael T Novak c/o Coleen Gerber Registration Counsel PeroxyChem, LLC 20005 Market Street, Suite 3200 Philadelphia, PA 19103

Subject: Label Amendment: Emerging Viral Pathogens Claim

Product Name: B-Cap 35 Antimicrobial Agent

EPA Registration Number: 72372-1 Application Date: March 17, 2020

Decision Number: 560842

Dear Mr. Novak.:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging\_viral\_pathogen\_program\_guidance\_final\_8\_19\_16\_001\_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

- 2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
- 3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
  - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
    - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
      - A. CDC Current Outbreak List for "U.S. Based Outbreaks" (www.cdc.gov/outbreaks),
      - B. CDC Current Outbreak List for "Outbreaks Affecting International Travelers" with an "Alert" or "Advisory" classification (www.cdc.gov/outbreaks) (also released through the CDC's Health Alert Network (HAN) notification process)
      - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
    - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page

(www.oie.int/wahis 2/public/wahid.php/Diseaseinformation/WI).

- A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is small non-enveloped, large non-enveloped, and enveloped.
- B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
- 4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE's publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

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5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use as a sterilant is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,

Steven Snyderman, Acting Product Manager 33

Regulatory Management Branch 1 Antimicrobials Division (7510P) Office of Pesticide Programs

Steven Inyderman

Enclosure: stamped label

# B-Cap<sup>™</sup> 35 Antimicrobial Agent

(ABNs: Durox, Durox LRA, Durox LRD, Durox LRA Type-S)

EPA Est. No		
For Industrial Use Only Not for human consumption or household		
ACTIVE INGREDIENT:		
Hydrogen Peroxide	35%	
OTHER INGREDIENTS:	<u>65</u> %	
TOTAL ·	100%	

## ACCEPTED

04/14/2020

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 72372-1

## KEEP OUT OF REACH OF CHILDREN **DANGER**

B-Cap™ 35 Antimicrobial Agent is for use as a sterilant in conjunction with Bioquell Hydrogen Peroxide Vapor (HPV) generating equipment. B-Cap™ 35 Antimicrobial Agent is for biofouling and slime control in:

- Pulp and paper mill systems
- Recirculating and once through cooling water systems
- Pasteurizer cooling water systems

**EPA Registration No. 72372-1** 

- **Process Waters**
- Biocidal control in packaging and storage vessels

B-Cap<sup>TM</sup> 35 Antimicrobial Agent is for use in aseptic food processing operations to achieve commerial sterilityof food packaging and equipment.

## **First Aid**

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

If swallowed: Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

## **Precautionary Statements**

## **Hazards to Humans and Domestic Animals**

DANGER: Corrosive, causes eye and skin damage. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Wash thoroughly with soap and water after handling. Do not breathe vapor or spray mist. Do not enter an enclosed area without proper respiratory protection. If concentrations in excess of the OSHA PEL TWA for hydrogen peroxide are expected, NIOSH approved (TC-19C) full face supplied air respirators must be worn. If the concentrations are unknown or could exceed the NIOSH IDLH of 75 PPM, then either NIOSH approved (TC-13F) Self- Contained Breathing Apparatus (SCBA) or supplied air respirators with escape bottles must be worn.

## **Environmental Hazards**

This pesticide is toxic to birds, mammals, fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Any solution released from the system should be diluted with water and tested for residuals to ensure that there is less than 3 ppm peroxygen remaining.

## **Physical or Chemical Hazards**

Strong oxidizing agent. Mix only with water. B-Cap<sup>TM</sup> 35 Antimicrobial Agent is not combustible; however, at temperatures exceeding 156°F, decomposition occurs releasing oxygen. The oxygen released could initiate or promote combustion of other materials.



PeroxyChem, LLC

<sup>(§)</sup> Peroxy<sup>Chem</sup> and B-Cap™ are trademarks of PeroxyChem, LLC

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

## STORAGE AND DISPOSAL

STORAGE: NEVER RETURN B-CAP<sup>TM</sup> 35 ANTIMICROBIAL AGENT TO THE ORIGINAL CONTAINER AFTER IT HAS BEEN REMOVED. Avoid all contaminants, especially dirt, caustic, reducing agents, and metals. Contamination and impurities will reduce shelf life and can induce decomposition. In case of a decomposition, isolate container, douse container with cool water and dilute B-Cap<sup>TM</sup> 35 Antimicrobial Agent with large volumes of water.

Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight. To maintain product quality, store this product in a cool and dry area. Do not store on wooden pallets.

### Procedure for Leak or Spill

Stop leak if this can be done without risk. Shut off ignition sources; no flames, smoking, flares, or spark producing tools. Keep combustible and organic materials away. Flush spilled material with large quantities of water. Undiluted material should not enter confined spaces.

## **Disposal**

**Pesticide Disposal:** If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods of disposal may vary by location, regulatory agencies should be contacted prior to disposal.

B-Cap™ 35 Antimicrobial Agent, which is to be discarded, should be disposed of as hazardous waste after contacting the appropriate local, state, or Federal agency to determine proper procedures.

## **Container Disposal**

Nonrefillable containers less than 5 gallons. Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into [application equipment or] a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Nonrefillable containers greater than or equal to 5 gallons. Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ½ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over into its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Empty drums are not returnable to PeroxyChem unless special arrangements have been made. Dispose of drums in accordance with local, state, and Federal regulations.

All Refillable containers. Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Return to PeroxyChem for reuse.

Note to reviewer – bracketed text is not applicable to automatic dispenser systems such as Bioquell Hydrogen Peroxide Vapor (HPV) generating equipment.

### B-Cap™ 35 Antimicrobial Agent

A microbiocide for use in controlling slime and sulfate forming bacteria in process waters, air washing systems, recirculating and once through water cooling towers and systems, including pasteurizer cooling water systems and industrial closed recirculating process water systems, and packaging and storage vessels.

## Air Washers and Recirculating and Once Through Cooling Water Systems, (cooling towers, evaporative condensers).

- 1. Severely fouled systems should be cleaned prior to treatment.
- 2. This product may be used in all types of cooling water systems that have mist-eliminating components. B-Cap<sup>TM</sup> 35 Antimicrobial Agent should be added at a point where uniform mixing can be achieved, for example the basin area. Addition may be intermittent or continuous. Hydrogen peroxide should not be mixed with other chemicals or additives without first checking for compatibility. Contamination with other chemicals could cause product decomposition.
  - Intermittent (Slug Dose) For severely fouled systems add 3 to 163 fl oz of B-Cap<sup>™</sup> 35 Antimicrobial Agent per 1000 gallons of water in the system, (10 to 500 ppm). Repeat until control is achieved. When control is evident add 1 to 31 fl oz of B-Cap<sup>™</sup> 35 Antimicrobial Agent per 1000 gallons of water in system (3 to 100 ppm H<sub>2</sub>O<sub>2</sub>) as needed to maintain control.
  - Continuous Feed Initial Dose: If the system is noticeably fouled, use slug dose procedure for the initial treatment. Once control is achieved, use a continuous feed of 0.3 to 16 fl oz B-Cap<sup>TM</sup> 35 Antimicrobial Agent per 1000 gallons of water per day in the system (1 to 50 ppm H<sub>2</sub>O<sub>2</sub>). Dosage rates should be increased or decreased depending on the extent of biofouling and control achieved.

## **Pasteurizer Cooling Water Systems**

The product can be used at the same application rates and in the same manner as described above. The solution should be added to the closed recirculating system at a point where uniform mixing can be achieved, e.g., basin, sump, or collection areas.

## **Biofouling Control in Pulp and Paper Mill Systems**

For use in the manufacture of paper and paperboard intended for non-food contact only. Not for use in the manufacture of paper and paperboard intended for food contact.

The product can be used to control bacterial, fungal and yeast growth in pulp, paper and paperboard mills.

- 1. Severely fouled systems should be cleaned prior to treatment with B-Cap<sup>TM</sup> 35 Antimicrobial Agent. Add B-Cap<sup>TM</sup> 35 Antimicrobial Agent directly to the system, don't mix with other chemicals or additives without first testing for compatibility. Contamination with other chemicals could result in product decomposition.
- 2. Add B-Cap™ 35 Antimicrobial Agent at a point in the system where it can be mixed uniformly with the pulp, e.g., the beater, hydropulper, fan pump, broke pump, etc.

Apply 1 to 40 fl oz of B-Cap™ 35 Antimicrobial Agent per ton of (dry basis) pulp or paper produced, (10 to 500 ppm H<sub>2</sub>O<sub>2</sub>). Addition may be continuous or intermittent depending on the type of system and severity of the biofouling.

#### **Process Water**

B-Cap<sup>™</sup> 35 Antimicrobial Agent may be used to aid in minimizing slime formation in process waters intended for use in precleaning hard non-porous surfaces, e.g., metals, glass or plastics prior to being painted, plated, or coated; cleaning pipes, equipment or other process equipment.

- 1. Add B-Cap™ 35 Antimicrobial Agent at a point in the system where it can be mixed uniformly. The quantity of product required will depend upon the severity of the fouling.
- 2. Apply 0.3 to 163 fl oz per 1000 gallons of water in the system (1 to 500 ppm). Once control is achieved, reduce application rate accordingly.

# Control of Slime, Bacteria, Fungi, and Other Microorganisms in packaging and storage vessels such as railcars, trucks, ships, totes, IBCs tanks, etc. used to contain clays, calcium carbonate, titanium dioxide, barium sulfate, and other filler materials.

- 1. If treating the container or vessel in the field, place the vessel or container on an area with an impervious surface with controlled runoff. Ensure that the antimicrobial treatment solution will not be released to the environment.
- 2. Remove gross contamination with a cleaner or other suitable detergent and rinse with water.
- 3. Prepare a dilute solution of the product by adding 1 to 4 volumes of B-Cap™ 35 Antimicrobial Agent to 11 volumes of potable water. This will provide solutions containing 3% to 10% hydrogen peroxide. Apply the diluted solution, at ambient or elevated temperatures, to the surface as a coarse spray, wipe/mop or flood to reduce bacterial and fungal contamination.
- 4. Allow antimicrobial agent to contact the surface for a period of time sufficient to ensure adequate cleaning. Depending on the microbial load, contact times can range from 5 to 30 minutes or longer.
- Drain dry. Do not rinse.

## B-Cap™ 35 Antimicrobial Agent is a sterilant for use in conjunction with Bioquell Hydrogen Peroxide Vapor (HPV) generating equipment.

#### [for container sizes 500 mL or larger]

The following directions are to be followed when using the Bioquell HPV equipment: The hydrogen peroxide vapor is intended for use as a sterilant in treating enclosures up to 3500 cubic feet (validated) or greater (non-validated). Use this product for sterilization as instructed in the Bioquell Use Manual. This product may not be used on food-contact surfaces unless followed by a potable water rinse.

## For Enclosures up to 35 cubic feet

- Ensure that all porous and non-porous surfaces are visibly clean and free from gross organic contamination.
- Connect the Bioquell HPV generator and add B-Cap™ 35 Antimicrobial Agent according to the Use Manual instructions. Seal the enclosure to be sterilized.
- 3. Apply B-Cap™ 35 Antimicrobial Agent at an injection rate of 3.1 g/minute for 55 minutes.
- 4. Allow vapor to remain for a minimum of 3 hours.
- 5. Aerate the chamber using the Bioquell HPV generator until hydrogen peroxide vapor is at or below 1.0 ppm. See the Bioquell Use Manual for complete instructions for aeration and recommended methods of measuring hydrogen peroxide vapor.

## For Enclosures Greater than 35 Cubic Feet to a Maximum of 3500 Cubic Feet

(Multiple 500 mL containers required for volumes greater than 35 cubic feet - refer to the table in item 3 below.)

- 1. Ensure that all porous and non-porous surfaces are visibly clean and free from gross organic contamination.
- Connect the Bioquell HPV generator and add B-Cap™ 35 Antimicrobial Agent according to the Use Manual instructions. Seal the enclosure to be sterilized.
- 3. Apply B-Cap™ 35 Antimicrobial Agent at an injection rate of 10 g/minute for 2.5 hours.

Ī	Volume to be B-Cap™ 35 Antimicrobial		Number of 500 mL
	treated		
		Agent required	Packages Required
	Up to 35 cubic feet	170.5 g	1
	36-3500 cubic feet	1500 g	3

- 4. Allow vapor to remain for a minimum of 15 minutes.
- 5. Aerate the chamber using the Bioquell HPV generator until hydrogen peroxide vapor is at or below 1.0 ppm. See the Bioquell Use Manual for complete instructions for aeration and recommended methods of measuring hydrogen peroxide vapor.

## [for 150 mL containers only]

The following directions are to be followed when using the rapid gassing HPV generator, the Bioquell QUBE. The hydrogen peroxide vapor is intended for use as a sterilant in treating enclosures up to 37 cubic feet. Use this product for sterilization as instructed in the Bioquell Use Manual. This product may not be used on food-contact surfaces unless followed by a potable water rinse.

## For Enclosures Up to 16 Cubic Feet

- 1. Ensure that all porous and non-porous surfaces are visibly clean and free from gross organic contamination.
- 2. Add B-Cap™ 35 Antimicrobial Agent according to the Use Manual instructions.
- 3. Apply B-Cap™ 35 Antimicrobial Agent at an injection rate of 6 g/minute until 26g has been injected.
- 4. Allow vapor to remain for a minimum of 10 minutes.
- 5. Aerate the chamber using hydrogen peroxide vapor is at or below 1.0 ppm. See the Bioquell Use Manual for complete instructions for aeration and recommended methods of measuring hydrogen peroxide vapor.

## For Enclosures Greater than 16 Cubic Feet to a Maximum of 37 Cubic Feet

- 1. Ensure that all porous and non-porous surfaces are visibly clean and free from gross organic contamination.
- 2. Add B-Cap™ 35 Antimicrobial Agent according to the Use Manual instructions.
- 3. Apply B-Cap™ 35 Antimicrobial Agent at an injection rate of 4 g/minute until 120g has been injected.
- 4. Allow vapor to remain for a minimum of 70 minutes.
- 5. Aerate the chamber using hydrogen peroxide vapor is at or below 1.0 ppm. See the Bioquell Use Manual for complete instructions for aeration and recommended methods of measuring hydrogen peroxide vapor.

### **Aseptic Food Processing Operations**

B-Cap™ 35 Antimicrobial Agent is a ready to use solution. It may be used to achieve commercial sterility of food packaging materials and food processing equipment.

Apply B-Cap<sup>TM</sup> 35 Antimicrobial Agent on the exterior and interior of food containers and closure systems (caps, seals, etc.), or appropriate food processing equipment surfaces. Use techniques such as, but not limited to, immersion, coarse spray, or circulations to sterilize the equipment. Apply B-Cap<sup>TM</sup> 35 Antimicrobial Agent at a minimum temperature of 75°C. The product must remain in contact with the packaging surface for a minimum of 20 seconds

Such use must comply with all applicable FDA regulations, including but not limited to 21 CFR parts 108, 110, 113, and 114. Use in an aseptic food processing operation includes testing required for the process validation. Food subject to these FDA regulations may not be sold in a treated package until after the scheduled process for the food processing operation has been accepted by the FDA.

## Control of Bacteria and Fungi in Dispersed Pigments and Synthetic and Natural Polymers in Aqueous Solutions

B-Cap™ 35 Antimicrobial Agent can be used to control bacteria and fungi in the manufacture and storage of dispersed pigments and aqueous polymers used in paint and paper production such as kaolin clay, titanium dioxide, calcium carbonate, calcium sulfate, barium sulfate, magnesium silicate, and kieselguhr and applications containing natural and synthetic polymer lattices based on acrylates, butadiene, PVA, styrene, and other monomers (e.g. water based emulsions, latexes, and dispersions).

Apply 1.3 to 8.9 gallons of B-Cap™ 35 Antimicrobial Agent solution to each 1,000 gallons of fluid. This will provide 500 ppm to 3,500 ppm of hydrogen peroxide. The hydrogen peroxide content for finished products is 0.05% (500 ppm) to 0.35% (3,500 ppm).

For open pouring systems, avoid breathing vapors, mist or gas. Be sure to use personal protective equipment including impervious gloves, impervious clothing and eye protection. Protective engineering solutions should be implemented and in use before PPE equipment is considered. This includes proper ventilation to maintain hydrogen peroxide levels below the OSHA PEL TWA of 1 ppm.

If concentrations in excess of the OSHA PEL TWA for hydrogen peroxide are expected, NIOSH approved (TC-19C) full face supplied air respirators must be worn. If the concentrations are unknown or could exceed the NIOSH IDLH of 75 PPM, then either NIOSH approved (TC-13F) Self- Contained Breathing Apparatus (SCBA) or supplied air respirators with escape bottles must be worn.

## [Emerging Viral Pathogens Claim – Hard, porous and non-porous surfaces]

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

(Note to the reviewer: The statements shall be made only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.)

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category[ies]:

- -Enveloped Viruses
- -Large Non-Enveloped Viruses
- -Small Non-Enveloped Viruses

For an emerging viral pathogen that is a/an	conjunction with Bioquell Hydrogen Peroxide	
Enveloped virus	Vapor (HPV) generating equipment. Use this	
Large, non-enveloped virus	product for sterilization as instructed in the	
Small, non-enveloped virus	Bioquell Use Manual according to the size of the space to be treated.	

B-Cap<sup>™</sup> 35 Antimicrobial Agent has demonstrated effectiveness as a sterilant which is defined in 40 CFR 158.2203 as "a substance, or mixture of substances, that destroys or eliminates all forms of microbial life in the inanimate environment, including all forms of vegetative bacteria, bacterial spores, fungi, fungal spores, and viruses". Thus, it is expected to be effective against viruses similar to [name of emerging virus] on hard, [porous and/or non-porous surfaces]. Therefore, BCap<sup>™</sup> 35 Antimicrobial Agent can be used against [name of emerging virus] when used in accordance with the directions for use as a sterilant on [hard, porous/non-porous surfaces]. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. As a sterilant, BCap™ 35 Antimicrobial Agent is expected to kill similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use as a sterilant on [hard, porous/non-porous surfaces]. Refer to the [CDC or OIE] website at [website address] for additional information.

Note: This product may not be used to sterilize medical devices.

In all applications, always prepare a new solution daily to ensure effectiveness. Do not reuse solutions. Dispose of any unused solution.

EMERGENCY TELEPHONE NUMBERS (24 HOURS)
MEDICAL: COLLECT 303-389-1409
CHEMTREC: 800-424-9300
OTHER: 281-474-8750

For more information see Safety Data Sheet

## **Proper Shipping Name:**

Hydrogen peroxide, aqueous solution with not less than 20 percent but not more than 40 percent hydrogen peroxide.

**UN 2014** 

4813-1495-7751, v. 2